

Clinical Applications of Magnetic Carriers”, Plenum Press, New York, 1597, ISBN 0-306-45687-7. In one embodiment the magnetic particle comprises a streptavidin-coated magnetic bead. The magnetic particles can be quite small, having at least one dimension ranging between 0.11 nm and 10,000 nm, preferably between 3 nm and 500 nm, and more preferably between 10 nm and 300 nm. The magnetic particles can acquire a magnetic moment due to an applied magnetic field (e.g., they can be paramagnetic) or they can have a permanent magnetic moment. The magnetic particles can be a composite, e.g., consist of one or more small magnetic particles inside or attached to a non-magnetic material, or a hetero/hybrid nanostructures, such as dumbbell-shaped magnetic gold nanoparticles, which are composed by one half of magnetic particle and another half of gold nanoparticle. As such, the term “magnetic particle” encompasses magnetic affinity complexes, coded magnetic affinity complexes, and coded magnetic signal affinity complexes, hybrid magnetic complexes, among others. In certain embodiments, the sample zone of the fluidic device comprises the magnetic particle. In other embodiments, different or the same magnetic particles can be contained within more than one fluidic zone.

[0034] As used herein, a “magnetic affinity complex” comprises a magnetic particle functionally coupled to an affinity agent. The term “affinity agent” generally refers to a molecule that binds to an analyte for the detection and/or analysis of the analyte and is described in more detail below. Non-limiting examples of affinity agents include example of affinity agents including antibodies, lectins, streptavidin, oligonucleotides, peptides, and oligosaccharides. It can be coupled to the magnetic particle using a functionalized polymer, for example.

[0035] A “coded magnetic affinity complex” comprises a magnetic particle functionally coupled to an affinity agent and to a code. A “code” is a recognizable structure/molecule such as a polynucleotide that correlates to the affinity agent and thus can be used to identify or quantify the analyte.

[0036] A “coded magnetic signal affinity complex” comprises a magnetic signal particle functionally coupled to an affinity agent and to a code. A “magnetic signal particle” is a nanoparticle having magnetic properties that is detectable by the detection element of the fluidic device. It can be detected by various means, including electrical sensing methods (i.e., FET), optical methods (UV-Vis, IR, Raman, fluorescence, chemiluminescence, evanescent, surface plasmon), magnetic imaging methods (such as MRI), enzymatic methods (production of a reaction product due to the interaction of a catalytic element with a reaction substrate, or alternatively, the amplification of a polynucleotide by PCR), and non-enzymatic chemical amplification methods.

[0037] A “signal particle” is a nanoparticle that is detectable by the detection element of the device, and thus encompasses signal affinity complexes, signal analyte complexes, and coded magnetic signal affinity complexes, among others. In certain embodiments the signal particle is a surface-enhanced Raman spectroscopy (SERS)-active nanoparticle, a fluorescent nanoparticle, a nanoparticle coupled to a surface-enhanced fluorescent tag, a MRI-active nanoparticle, a nanoparticle containing contrast reagents, or a core nanoparticle covalently coupled to a catalytic element or an optical tag. In one embodiment, the signal particle is a COIN (composite organic-inorganic nanoparticles) particle. In other embodiments, the signal particle is a Qdot (quantum dot), or another fluorescent nanoparticle, such as SEF (surface-enhanced fluorescence) nanoparticle or a FluoDot™. In further

embodiments, the signal particle is any nanoparticle (i.e. gold, silver, CdS, CdSe, copper, Eu³⁺-coated polymer, an organic polymer (homo or hetero), polymer particles incorporated with organic dyes, an inorganic compound, or composite compounds, etc.). When covalently coupled to an optical tag, the nanoparticle is an “optical nanoparticle”. Additionally, the SERS-active nanoparticle and fluorescent nanoparticle can also be functionally coupled to a catalytic element. In certain embodiments, the sample zone of the fluidic device comprises the signal particle. Alternatively, the sample particle is contained within another fluidic zone. In further embodiments, different or the same signal particles can be contained within more than one fluidic zone.

[0038] A “signal affinity complex” comprises a signal particle functionally coupled to an affinity agent. A “signal analyte complex” refers to a signal particle functionally coupled to an analyte. An “analyte” refers to a molecule or biological cell of interest that is to be analyzed or detected using the devices and methods described herein, and is described further below.

[0039] A “catalytic element” is a compound that serves as an agent to cause a chemical reaction to occur in a reaction substrate, where the reaction product is detectable by the detection element. In certain embodiments, the catalytic element is selected from the group consisting of alkaline phosphatase, horseradish peroxidase, glucose oxidase, firefly luciferase, *Renilla luciferase*, bacterial luciferase, other enzymes or analogs or combinations thereof.

[0040] The catalytic element can be conjugated to the signal particle through a functionalized polymer. For example, a polymer with a functional group (i.e. aldehyde, amine, carboxylic acid, biotin) is used to conjugate the affinity agent and/or catalytic element to the signal particle. Conjugation can be through non-covalent interactions such as hydrophobic or electrostatic interactions, or through covalent interactions, such as amide bond formation.

[0041] The analyte interacts with the magnetic particle and/or signal particle to form a binding complex, which includes any combination of the above-described magnetic particles and signal particles. Binding complexes include, for example, sandwich binding complexes, magnetic binding complexes, signal binding complexes, competitive binding complexes, coded magnetic binding complexes, and coded magnetic signal binding complexes.

[0042] A “sandwich binding complex” comprises a magnetic affinity complex, a signal affinity complex, and an analyte. For example, a sample suspected of comprising an analyte is introduced into the sample zone of the fluidic device. The analyte interacts sequentially or simultaneously with a magnetic affinity complex and a signal affinity complex to form a sandwich binding complex. Typically the affinity agent coupled to the magnetic particle is different than the affinity agent coupled to the signal particle, although both are complementary to the analyte. The microcoil array is activated to move the sandwich binding complex to the detection zone. Uncomplexed signal particles are left behind without being transported. The signal detected from the sandwich binding complex indicates the presence of the analyte. Typically this method is useful for determining the presence of proteins (including peptides, antibodies and autoantibodies) or nucleic acids.

[0043] A “super-binding complex” comprises a magnetic affinity complex, analyte, a coded affinity complex, and a signal affinity complex. For example, a sample suspected of